


Serial No.: 10/076,213
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Respectfully submitted,

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Dated: 4/26/02


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Serial No.: 10/076,213
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VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 9. (New) A process for minimizing thermal aggregation of DNase in a liquid solution comprising introducing a DNase aggregation-inhibiting amount of sugar to a solution comprising DNase, and elevating the temperature of said DNase solution above 37°C temperature.
10. (New) A process according to claim 9, wherein the temperature of said solution is elevated above about 60°C.
11. (New) A process according to claim 9, further comprising reducing the pH of said solution below pH 7.0.
12. (New) A process according to claim 11, wherein said solution is at about pH 6.5.
13. (New) A process according to claim 11, wherein said solution is at about pH 6.
14. (New) A process according to claim 11, wherein said solution is at about pH 5.
15. (New) A process according to claim 9, wherein said sugar is present in an amount from 50 mg/ml to 200 mg/ml.

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16. (New) A process according to claim 9, wherein said sugar is α -lactose monohydrate, mannitol, trehalose or sucrose.
17. (New) The process according to claim 9, further comprising the steps of spray-drying said liquid solution and collecting the spray-dried product as a respirable DNase-containing powder that is therapeutically effective when administered into the lung of an individual.
18. (New) A DNase solution comprising DNase and a DNase aggregation-inhibiting amount of sugar wherein said DNase solution is minimally aggregated when said solution is at a temperature greater than 37°C.
19. (New) A DNase solution according to claim 18, wherein the temperature is greater than about 60°C.
20. (New) A DNase solution according to claim 18, wherein said solution is further kept at a pH below 7.0.
21. (New) A DNase solution according to claim 20, wherein said solution is at about pH 6.5.
22. (New) A DNase solution according to claim 20, wherein said solution is at about pH 6.

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23. (New) A DNase solution according to claim 18, wherein said sugar is present in an amount from 50 mg/ml to 200 mg/ml.
24. (New) A DNase solution according to claim 18, wherein said sugar is α -lactose monohydrate, mannitol, trehalose or sucrose.
25. (New) A DNase solution according to claim 18 that is further spray-dried to a respirable DNase-containing powder that is therapeutically effective when administered into the lung of an individual.--